



December 30, 2016

Endologix Provides Physicians with Updated Information about the AFX® Endovascular AAA System

IRVINE, Calif., Dec. 30, 2016 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, today issued a letter to physicians with updated information about the AFX® Endovascular AAA System.

Guidance to Physicians

The voluntary letter, issued after discussions with the U.S. Food and Drug Administration, reviews data from the commercial experience since the original introduction of AFX in 2011. It provides guidance for physicians in the monitoring and post-operative care of patients to address an increased rate of Type III endoleaks with the first-generation AFX device (with "Strata" graft material), for which manufacturing ceased in 2014. It also includes a voluntary recall of the limited number of first-generation AFX devices remaining in inventories, and some sizes of AFX2 related to the Company-issued product hold announced earlier this week, which was based on a manufacturing issue identified during routine internal quality control testing. The Company has identified the issue, released all sizes of AFX and some sizes of AFX2 from the hold, and developed a plan to release the remaining sizes of AFX2 as soon as possible.

The letter also describes the enhancements that have been made to the newer AFX and AFX2 devices, updated instructions for use (IFU), and the positive initial impact of those enhancements. A copy of the letter is available in the healthcare professionals section of the company's website at www.endologix.com.

"Endologix is deeply committed to patient safety and excellent clinical outcomes," said Endologix Chief Executive Officer John McDermott. "We will continue to develop, manufacture and test devices to the highest quality standards and conduct clinical research and post-market surveillance programs to actively monitor the clinical experience of all our devices. The physician letter and recent temporary hold on AFX/AFX2 demonstrates our unwavering commitment to physicians and patient safety. We look forward to releasing the remaining sizes of AFX2 and working with our notified body to make AFX and AFX2 available in Europe as soon as possible."

The Company also reiterated that the letter regarding the older first-generation AFX device is entirely separate from the hold currently in place for some sizes of AFX2. The recent hold was voluntarily initiated by the Company as a precaution based on internal quality control testing and was not based on any reports of adverse clinical results. To date, the reported rates of Type III endoleaks with the current version of AFX (with Duraply) and AFX2 are very low.

About Endologix, Inc.

Endologix, Inc., develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is endovascular stent grafts for the treatment of abdominal aortic aneurysms (AAA). AAA is a weakening of the wall of the aorta, the largest artery in the body, resulting in a balloon-like enlargement. Once AAA develops, it continues to enlarge and, if left untreated, becomes increasingly susceptible to rupture. The overall patient mortality rate for ruptured AAA is approximately 80%, making it a leading cause of death in the United States. Additional information can be found on Endologix's website at www.endologix.com.

Forward-Looking Statements

This communication includes statements that may be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to clinical results obtained with Endologix's newer AFX devices, the release of additional sizes of AFX2 and regulatory timelines, the accuracy of which are necessarily subject to risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Endologix. Many factors may cause actual results to differ materially from anticipated results, including unanticipated clinical outcomes, unexpected delays in process improvements and additional regulatory requirements. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Endologix undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Endologix's Annual Report on Form 10-K for the year ended December 31, 2015, and Endologix's subsequent filings with the Securities and Exchange Commission, for more detailed information regarding these risks and other factors that may cause actual results to differ materially from those expressed or implied.

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